LUMBAR EPIDURAL INJECTIONS

Noridians' Response to Provider Recommendations (for comment period ending 11/06/2013):

Comment: One provider, citing literature from Deyo and others, indicated the published literature on both subacute and chronic low back pain is insufficient to support the use of injection therapy. Moreover, guidelines from US and Europe do not recommend injection therapy for chronic low back pain.

Response: Medicare will cover epidural injections. Medicare agrees the overall literature is weak and also acknowledges the positive findings, including surgery-sparing, of a number of well-designed and executed studies in patients with radicular pain. The data supporting the use of ESIs in the treatment of axial low back pain without radicular origin is poor. Hence, coverage primarily is restricted to LBP with radiculopathy. Further, the use of imaging guidance, particularly fluoroscopy or computed tomography, with the use of injectable radio-opaque contrast material has been shown to enhance the accuracy and safety of needle placement for all ESI procedures and is a requirement of this LCD.

Comment: Several commenters recognized the LCD addressed all lumbar epidurals and requested the title be updated.

Response: The title now is "Lumbar Epidural Injections," consistent with the narrative and coding.

Comment: Some providers requested coverage be restricted to the caudal approach only.

Response: Medicare will not accept the request. The literature does not demonstrate the superiority of the caudal approach over other approaches .The caudal approach appears to be equivalent to interlaminar epidural injections when fluoroscopy is not used but inferior to transforaminal injections in producing analgesia than caudals.

Comment: Some providers requested clarification on the application of this LCD to selective nerve root blocks (SNRBs).

Response: This policy describes appropriate coverage of selective nerve root blocks in the lumbar spinal region. (Please see section on diagnostic transforaminal injections.) This coverage is consistent with that previously described in Noridian's long-standing Nerve Blockade LCD, which currently is posted as a draft LCD for JE.

Comment: One provider asked what clinical picture should make one suspect radicular pain.

Response: Pain "radiated"" along the dermatome (sensory distribution) of a nerve suggests radicular pain. Definition will be added to LCD.

Comment: Several providers objected to coverage of moderate sedation during the performance of lumbar epidurals; especially, for diagnostic blocks. On the other hand, some providers requested that all forms of sedation and general anesthesia be covered.

Response: Medicare will cover these forms of sedation when medically reasonable and necessary for an individual patient as evidenced by clear and compelling medical records' documentation of the specific patient's need for this level of sedation. Medicare understands the risk(s) of eliminating or blunting the response to nerve contact/partial injection.

Comment: Some providers and one coder suggested the addition of codes for the treatment of pain associated with herpes zoster and removal of the code for post-laminectomy syndrome.

Response: Medicare accepts the recommendations. Pain associated with herpes zoster is mediated by the spinal nerves and may be treated with lumbar injections. The medical literature does not demonstrate the efficacy of epidural injections in the treatment of post-laminectomy syndrome.

Comment: One Society requested restriction of epidurals to local anesthetic (LA) injections only, indicating steroid injection is both harmful and unnecessary.

Response: Medicare rejects the request. Medicare agrees the injection of steroids carries considerable risk. However, while the medical literature demonstrates the pain-relieving efficacy of LA injections administered by the interlaminar and caudal routes, the administration of steroids produces more intense and longer-lasting pain relief following transforaminal placement, which is greater than that produced following interlaminar or caudal injection and transforaminal injection with LA alone.

Comment: One provider requested elimination of the requirement for imaging.

Response: While there is no requirement for imaging during interlaminar and caudal injections when steroids are not injected, Medicare will retain the requirement for all transforaminal injections and all epidural injections of steroids (ESIs). The use of this type of image guidance is considered an integral part of transforaminal injections, which cannot reliably be performed without image guidance. The use of imaging guidance, particularly fluoroscopy or computed tomography, with injectable radio-opaque contrast material has been shown to enhance the accuracy and safety of needle placement for all ESI procedures. Also, as with other medical procedures, there are specific risks associated with the performance of ESIs, both arising from the procedures themselves as well as the injected agents. These include the potential for allergic reactions, intravascular placement with complications that can include neurologic injury, violation of the dural membrane with the potential for leaks of cerebrospinal fluid or further

neurological injury, infection, and systemic reactions or side effects resulting from the biological effects of corticosteroids. When considering the presence of these risks alongside the potential for benefit, both patient selection and appropriate image guidance/contrast verification is of paramount importance in order to minimize risks while treating those individuals for whom ESIs offer significant potential benefit. These factors are reflected in the coverage considerations that follow.

Comment: One provider group requested the elimination of the requirements for level of pain assessments and documentation of the patient's failure to respond to conservative measures. The group indicated they could "no know what level of documentation has been done by the ordering doctor."
Response: The request is rejected. While a good deal may be said related to the ethics of this comment, from a payment perspective only, no provider may bill a service unless the provider personally establishes the service is medically indicated as confirmed and documented in the medical records by the service provider with appropriate history-taking and patient examination. At a minimum, at the time the service is delivered, Medicare expects to see an interval update to the more comprehensive examination performed and documented by the referring provider. It is the expectation of Medicare that the provider performing the intervention has seen and reviewed and, hence, has access to the referring provider's assessment. If Medicare requests medical records for review, *all* records which establish the need for the service must be submitted, regardless of who generated the documentation or where the documentation was generated or stored.

Comment: One provider requested transforaminal injections not be restricted as diagnostic tests only.

Response: Transforaminal injections may be therapeutic as well as diagnostic. This LCD does not restrict their use as therapeutic options.

Comment: One provider requested coverage for epidurals without another 4-week trial of conservative measures when previous medication-responsive pain recurs. Provider reminded us that sciatic and other low back pain commonly waxes and wanes and that recurrence should allow treatment with epidurals, even if conservative measures had alleviated the pain in the past.

Response: This LCD could cover the use of epidurals in this situation without another 4 week trial. Medicare agrees that many types of chronic low back pain wax and wane, often spontaneously remitting; and remissions thought to be related to either treatment with oral medications or epidurals, with or without steroids, commonly only last a few months. If pain recurs in a short time frame (weeks), this may be seen as at least a partial treatment failure. We expect providers would add another treatment or change treatments.

Comment: One provider suggested Medicare limit image guidance to fluoroscopy to control costs. Provider also suggested we require peer review of procedures by hospital, Medicare, or Ambulatory Surgical Center.

Response: Medicare cannot implement the suggestions. Contractors' coverage determinations must be based on the medical reasonability and necessity of a service not cost. The medical literature demonstrates that both fluoroscopy and CT imaging increase the accuracy and success of epidural injections, with neither imaging procedure demonstrating superiority. Regarding medical review, providers are always subject to potential pre and post-payment records' review in Medicare, which is undertaken for a variety of reasons by a variety of Contractors (e.g., MAC, RAC, ZPIC, OIG, etc.) Medicare may not require non-Medicare entities review services delivered.

Comment: Some providers requested the elimination of the restriction on the number of levels that may be treated with transforaminal injections. Other providers and one Society thought the requirement too liberal while other responses from Specialty Societies supported the requirement.

Response: Medicare will not eliminate this requirement. There is no evidence that supports three (3) level transforaminal injections and only one reference in the medical literature that supports the performance of bilateral two (2) level transforaminal injections; the level of evidence is poor. Performance of more than one level bilaterally or two levels on one side floods the area with anesthetic or steroid, negating the diagnostic utility of the injections, any possibility of specificity (which is the justification for the use of transforaminal injections), and exposes patients to a high steroid load with all attendant potential complications.

Comment: A provider requested elimination of the restriction on number of types of injections that may be performed per session. Provider cited an article demonstrating the failure of LA/steroid spread from L3-4 injection to L5 nerve roots 50% of the time as shown by contrast. The provider also noted that caudal injections may skip a neuroforamen. Provider has done caudals and covers nerve roots with transforaminal injections.

Response: Medicare will not eliminate the restriction and does urge the use of contrast in all injections to verify spread and allow correction at the time of the injection. The article cited, published in 1973, reported findings after injections without image guidance and potentially with inadequate volumes of injectate and underlined the importance of volume and contrast**.** Medicare agrees the spread of epidurally injected LA and/or steroid is variable and requires the use of contrast for all steroid injections and all transforaminal diagnostic blocks. Medicare will not reimburse more than one type of injection per session. In cases where spread is inadequate, identification of inadequate spread (such as by use of contrast) in many cases allows augmentation or other correction.

Comment: Commenters were divided in the response to the six (6) per year limitation on the total number of lumbar epidurals allowed. Some believe the limit "way too high" and others requested removal of any limitation. Others strongly supported any limitation as long as some limitation was established.

Response: The six (6) per year limit allows for several diagnostic blocks (transforaminals) if needed and which shares the same code as a therapeutic transforaminal injection.

Comment: Several providers requested elimination of "physician"- specific language and questioned the authority of MACs to determine provider qualifications for service delivery.

Response: In accordance with the Medicare statute, the benefit category for the services addressed in this LCD is "Physician Services" (SSA 1861). When the designation is used, it indicates any eligible provider of the services and may include for example, MDs, DOs, NPs, CRNAs, CNS', PAs. The statute allows reimbursement for the "Physician Services" addressed in this LCD if both the services and the providers meet the medical necessity requirements described in the statute, which are interpreted and applied by the MACs in accordance with the statute (SSA 1862(a)(1)(A).